

5

LESS-INVASIVE DEVICES AND METHODS FOR CARDIAC VALVE SURGERY

Cross-Reference to Related Applications

- This application is a continuation of co-pending application Serial No.
- 10 08/594,870, filed January 31, 1996, which is a continuation-in-part of Serial No. 08/485,600, which is a continuation-in-part of Serial No. 08/281,962, now abandoned, which is a continuation-in-part of Serial No. 08/163,241, now U.S. Patent No. 5,571,215, which is a continuation-in-part of Serial No. 08/023,778, now U.S. Patent No. 5,452,733. This application is also a continuation-in-part of Serial No.
- 15 08/486,941, now U.S. Patent No. 5,799,661. The complete disclosure of each of the above-referenced applications is incorporated herein by reference for all purposes.

Field of the Invention

- The present invention relates generally to surgical instruments, and more specifically, to surgical instruments for less-invasive surgery of the heart and great vessels, especially instruments for repair and replacement of heart valves.

Background of the Invention

- The present invention is directed to devices and techniques for the surgical treatment of heart valve disease, and particularly aortic valve disease. The aortic valve separates the left ventricle of the heart from the aorta, which carries oxygenated blood to the arterial system. Normally, when the left ventricle contracts during systole, the aortic valve opens to allow blood to flow into the aorta. During diastole, when the left ventricle returns to its uncontracted state, the aortic valve closes to prevent blood from flowing from the aorta back into the heart.

In aortic valve disease, the aortic valve is compromised due to calcification of the valve leaflets, congenital deformation of the valve, or other conditions such that the valve does not completely open or close normally. As a result, the valve restricts blood flow out of the heart during systole, or the valve allows blood flow back into

the heart during diastole. If the condition becomes sufficiently severe, surgical treatment is frequently required.

- Various surgical techniques have been used to repair aortic valves. In conventional "open-chest" approaches, a large opening is formed in the chest--known
- 5 as a sternotomy or thoracotomy--the patient's heart is arrested while circulation is supported by a cardiopulmonary bypass system, an incision is formed in the aorta, and instruments are then used to decalcify the valve, to separate valve leaflets which are fused together, or to constrict the annulus of an enlarged valve. Less-invasive approaches to valve repair have also been proposed. Balloon valvuloplasty, for
- 10 example, involves the use of a balloon catheter threaded from a peripheral artery into the aorta, and expansion of a balloon within the calcified aortic valve to separate the valve leaflets while the heart remains beating. Unfortunately, aortic valve repair techniques have not had long-lasting success in preventing recurrence of the disease, and eventual replacement of the valve is frequently required.
- 15 The most widely-accepted surgical technique for the treatment of severe aortic valve disease is aortic valve replacement. In aortic valve replacement surgery, the diseased aortic valve is replaced with a prosthetic valve, homograft, allograft, or other type of replacement valve. Conventional aortic valve replacement techniques require a sternotomy or thoracotomy to be formed so as to provide access into and
- 20 visualization of the chest cavity. The patient is placed on cardiopulmonary bypass, and the heart is stopped using an aortic cross-clamp to block blood flow through the aorta while a cardioplegic fluid is injected into the aorta upstream of the cross-clamp or into the coronary sinus on the venous side of the heart. An incision is then made in the ascending aorta near the aortic valve, and the native valve leaflets are removed
- 25 using surgical scissors inserted through the aortic incision. Specialized instruments may also be used to debride the valve annulus. A replacement valve is then sutured in place at the native valve position.

While aortic valve replacement is frequently effective in treating aortic valve disease and can add ten or more years to the life of a patient having the disease, the

30 procedure also suffers from significant drawbacks surrounding the invasiveness and trauma of the surgery. The large thoracotomy required by the procedure is highly invasive, produces a great deal of pain, heightens the risk of infection and other complications, increases costs, and lengthens hospital stay considerably.

- What is needed, therefore, are devices and techniques for the surgical treatment of aortic valve disease, especially for performing aortic valve replacement, which do not suffer from the drawbacks of conventional open-chest aortic valve surgery. Most desirably, the devices and techniques should obviate the need for a
- 5 sternotomy and minimize the size of any necessary thoracic incisions to eliminate the pain, trauma, risks, costs, and lengthy recovery time associated with conventional aortic valve surgery. At the same time, the devices and techniques should facilitate replacement of a diseased aortic valve with the same types of replacement valves which currently enjoy wide acceptance for aortic valve replacement, including
- 10 mechanical valves, bioprosthetic valves, homografts, allografts, and others.

Summary of the Invention

- The invention provides devices and methods for performing heart valve surgery which eliminate the need for a median sternotomy or other type of
- 15 thoracotomy. The devices and methods are particularly advantageous in that they facilitate surgical repair or replacement of a heart valve in a manner analogous to the widely-accepted surgical techniques used in open-chest valve repair or replacement, yet without the invasiveness, pain, risks, and recovery time of conventional techniques. Advantageously, the devices and methods facilitate replacement of a
- 20 diseased heart valve using various types of commercially-available replacement valves with proven safety and effectiveness. The devices and methods of the invention are perhaps most useful for the repair and replacement of the aortic valve, but may be used for the surgical treatment of any of the valves of the heart, as well as in other surgical procedures within the heart and great vessels of the thorax.
- 25 In one aspect of the invention, a method is provided for accessing an internal chamber of a patient's heart through a vessel in fluid communication with the chamber. The method includes visualizing the vessel through a percutaneous access port between two adjacent ribs. An instrument is positioned into an inner lumen of the vessel through a penetration in a wall of the vessel. The proximal end of the
- 30 instrument extends out of the patient's chest through a percutaneous access port between the ribs, and the proximal end of the instrument is then manipulated to position the distal end of the instrument through the vessel and into the internal chamber of the heart. With the instrument within the internal chamber, various types

of inspection, diagnostic and interventional procedures may then be performed. All manipulations of the instrument are performed with the surgeon's hands outside of the patient's chest, and none of the ribs or the sternum are cut or removed during each step. Preferably, in fact, none of the ribs or the sternum are significantly retracted

- 5 from their natural undeflected positions during the procedure. Visualization is accomplished either by looking directly into the chest through an access port between the ribs, by introducing a thoracoscope through such an access port and viewing a video image of the vessel and heart on a monitor, or by using other available less-invasive visualization devices.

- 10 In a preferred embodiment, the vessel is the aorta, the chamber is the left ventricle of the heart, and the distal end of the instrument is positioned into the aorta, through the aortic valve, and into the left ventricle. The instrument may then be used to perform a procedure in the heart or on the aortic valve itself. For example, the instrument could be used for repairing a diseased aortic valve, and may comprise a
15 debridement device for removing calcium from the valve annulus or leaflets, a scissors for incising the leaflet commissures to separate the leaflets, a cutting device for resecting the valve leaflets, or a needle driver for applying a suture to the valve annulus to reduce the diameter of the valve.

- In a particularly preferred embodiment, the instrument is used in the
20 replacement of a diseased aortic valve. The instrument may be a scissors, rongeur, knife or other cutting instrument for removing the native valve leaflets, or a needle driver or other device for applying sutures to the native valve annulus which are used to secure a replacement valve at the aortic valve position. The instrument could alternatively comprise a valve sizing device for measuring the size of the native valve
25 annulus, or a valve delivery instrument for positioning a replacement valve at the aortic valve position. In any case, the instrument extends from the left ventricle out of the chest through a percutaneous access port between two ribs, and is manipulated entirely from outside of the chest.

- As another alternative, the instrument may comprise any of a variety of
30 devices for performing diagnostic or interventional procedures within the heart, such as an angioscope or other endoscopic visualization device, an electrophysiological mapping or ablation device, or a laser for transmyocardial revascularization.

Additionally, the instrument could be used to repair or replace other valves of the

heart. For example, the mitral valve could be repaired or replaced by positioning the instrument through the aorta and left ventricle to the mitral position (and through the mitral valve into the left atrium if necessary). Or, an instrument could be positioned through the superior vena cava or the inferior vena cava into the right atrium to

- 5 perform a procedure on the right side of the heart, including repair or replacement of the tricuspid valve between the right atrium and right ventricle, or repair or replacement of the pulmonary valve between the right ventricle and the pulmonary artery. Various other procedures may also be performed according to the method of the invention, including pulmonary thrombectomy, the Cox "maze" procedure for
- 10 treatment of atrial fibrillation, and repair of congenital defects such as atrial and ventricular septal defects or patent ductus arteriosus.

In many of the procedures which may be performed using the methods of the invention, the patient is placed on cardiopulmonary bypass and the heart is arrested. First, general anesthesia is administered. To establish cardiopulmonary bypass, an

- 15 arterial cannula is placed into a peripheral artery, usually a femoral artery, and a venous cannula is placed in a peripheral vein, usually a femoral vein. The arterial and venous cannulae are connected to a cardiopulmonary bypass pump and oxygenator, allowing deoxygenated blood to be withdrawn from the venous system through the venous cannula, oxygenated, and then pumped back into the patient's arterial system
- 20 through the arterial cannula.

The heart may then be arrested in any of several ways. In an endovascular technique, an aortic catheter is introduced into a peripheral artery selected from among the femoral, brachial or subclavian arteries. The aortic catheter is advanced transluminally into the ascending aorta, and an expandable member such as a balloon

- 25 is expanded in the ascending aorta to block blood flow through the aorta. A cardioplegic fluid is then delivered into the ascending aorta upstream of the expandable member so as to perfuse the myocardium via the coronary arteries.

Alternatively, a thoracoscopic aortic occlusion device may be used to arrest the heart. The thoracoscopic aortic occlusion device may be an external clamp positionable

- 30 through a percutaneous access port between two ribs and around the exterior of the aorta, the clamp being movable between an open position and a closed position in which it clamps the aorta to occlude the aortic lumen. A cardioplegic fluid is then delivered into the aorta upstream of the clamp, either through a cannula penetrating

the aortic wall and extending out of the chest through an intercostal access port, or through an endovascular catheter extending into the ascending aorta from a peripheral artery. The thoracoscopic aortic occlusion device may alternatively comprise a shaft having an expandable member such as a balloon mounted to its distal end which is

5 configured to be introduced into the aorta through a small incision or puncture in the aortic wall. The expandable member may be expanded within the aorta to occlude the aortic lumen, and a cardioplegic fluid then delivered upstream of the clamp through either a thoracoscopic cannula or endovascular catheter.

In many cases, in order to maintain cardioplegic arrest, it will be desirable to

10 deliver cardioplegic fluid to the myocardium in a retrograde manner via the coronary sinus instead of or in addition to antegrade delivery from the ascending aorta. In these cases, an endovascular catheter is introduced transluminally into the coronary sinus, which drains into the right atrium of the heart, from a peripheral vein such as the femoral, subclavian or internal jugular vein. The endovascular catheter preferably has

15 a balloon or other occluding member on its distal end for occluding the coronary sinus during delivery of cardioplegic fluid. Usually, the occluding member is expanded while cardioplegic fluid is delivered, then contracted to allow fluid to drain into the right side of the heart from the capillary beds feeding the myocardium.

With the heart arrested and circulation of blood supported by cardiopulmonary bypass, the patient is prepared for a surgical procedure conducted in accordance with the principles of the invention. One such procedure is replacement of the aortic valve. In a method of aortic valve replacement according to the invention, a valve prosthesis is positioned through a percutaneous access port between two adjacent ribs and through an incision in a wall of the aorta using a first instrument. The valve

25 prosthesis is then attached at the aortic valve position between the left ventricle and the aorta using at least a second instrument. All instruments used in the procedure are manipulated only from outside of the chest, and neither the ribs nor the sternum are cut or removed during the procedure. Visualization of the vessel and heart is accomplished, as described above, by direct vision through an access port, or using a

30 thoracoscope or other minimally-invasive visualization device.

In a preferred embodiment, the first instrument comprises a delivery handle which is coupled to the valve prosthesis, or to a holder on which the valve prosthesis is mounted. The delivery handle is configured to allow the valve prosthesis to be

introduced into the chest through the percutaneous access port and has a length selected to reach the aortic valve position from outside of the chest. Usually, the valve prosthesis is introduced from the first, second, third, or fourth intercostal space on the anterior side of the chest, and the delivery handle is at least about 20 cm in

5 length. In a specific embodiment, the valve prosthesis is movably coupled to the delivery handle such that it may be positioned through the access port between the ribs in a first orientation, then re-oriented within the chest relative to the delivery handle into a second orientation suitable for attachment at the aortic valve position. Preferably, the delivery handle has an actuator on its proximal end to allow the valve

10 prosthesis to be reoriented by moving the actuator outside of the patient's chest.

The valve prosthesis is preferably coupled to the delivery handle in such a way that it may be positioned through an intercostal space without removing or retracting the ribs significantly. In a preferred embodiment, the valve prosthesis is mounted such that an axis extending axially through the middle of the sewing ring of the valve

15 prosthesis is approximately perpendicular to the longitudinal axis of the delivery handle. In this way, the profile of the valve prosthesis and delivery handle in a plane perpendicular to the longitudinal axis of the delivery handle is minimized. For some types of replacement valves, however, even in this orientation, the profile of the valve and handle will be large enough that some minor retraction of the adjacent ribs may

20 be required to allow the valve to be introduced into the chest without risking damage to the valve.

The percutaneous access port through which the valve prosthesis is positioned may comprise a puncture or incision through the chest wall between the ribs which does not involve cutting or removing the ribs or the sternum adjacent to the incision.

25 Preferably, no significant retraction or displacement of the ribs or sternum will be necessary. In most cases, the tissue adjacent to the access port will need to be retracted or separated to provide an opening into the chest which will not interfere with introduction of the valve prosthesis and through which the surgeon may view the chest cavity. For this purpose, the invention provides a retraction device particularly

30 well-suited for aortic valve replacement. In a preferred embodiment, the retraction device comprises a cannula having a distal end suitable for placement between the ribs into the chest, a proximal end, and a passage therebetween configured to allow the valve prosthesis to be easily passed through it. In a preferred configuration, the

passage in the cannula has a cross-sectional height which is substantially greater than its cross-sectional width, preferably at least about 1.5 times the cross-sectional width. In this way, the cross-sectional height may be large enough to accommodate the outer diameter of the valve prosthesis in the passage, while the cross-sectional width is

5 small enough to fit between the ribs without significant retraction (yet being large enough to accommodate the height of the valve prosthesis when mounted to the delivery handle).

If a replacement valve having a larger profile is to be used requiring some minor retraction of ribs, the retraction device of the invention may be adjustable in

10 width to provide a slightly larger passage into the chest while the valve is introduced, deflecting the ribs adjacent to the access port as needed. Once the replacement valve is within the chest cavity, the retraction device may be returned to a smaller width in which the ribs are in their natural, undeflected positions for the remainder of the procedure.

15 The retraction device of the invention may further include a suture organizer mounted to it for arranging the sutures used to secure the valve prosthesis in the aortic valve position. In a preferred embodiment, the suture organizer is mounted to the proximal end of the cannula through which the valve prosthesis is positioned, whereby a plurality of sutures may be drawn out of the chest cavity through the

20 passage in the cannula and placed in spaced-apart locations on the suture organizer. The suture organizer may comprise, for example, a ring having a plurality of radial slots arranged about its perimeter each of which is configured to receive and retain a suture thread.

Usually, the native valve leaflets are excised from the native annulus and any

25 calcium or other debris on the annulus is removed before a replacement valve is implanted. To remove the valve leaflets, thoracoscopic scissors and forceps may be introduced through a percutaneous access port and used to cut the leaflets from the annulus. Specialized thoracoscopic debridement devices, such as rongeurs having an inner lumen through which suction may be applied, are then used to cut away calcific

30 deposits and other undesirable matter from the surface of the valve annulus. During this process a filter or trap may be placed through the aortic valve into the left ventricle to catch any debris which may be released.

In most cases, the native valve annulus must be measured to ascertain the appropriate size of the valve prosthesis to be used. This is accomplished by utilizing a specialized valve sizing device which may be introduced through a percutaneous access port and positioned adjacent to or advanced through the native annulus. The

5 sizing device preferably includes an elongated handle with a sizing disk of a known size at its distal end which may be compared to or positioned within the native annulus. The sizing disk may be adjustable in diameter to measure a range of sizes, may include markings for visual identification of the size of the annulus, or may be interchangeable with larger and smaller sizing disks to allow multiple sizes to be tried

10 until the proper one is found. The sizing disk is mounted to the distal end of the handle in such a way as to be positionable into the chest without retracting or removing ribs, and is preferably pivotably attached to the handle so as to be movable into a low profile orientation for introduction, or is collapsible for introduction and then expandable for sizing the valve annulus.

15 A variety of different replacement valves may be implanted using the devices and methods of the invention, including mechanical prostheses, bioprostheses, homografts and allografts. Advantageously, the invention facilitates the use of many of the clinically-proven replacement valves currently used in open-chest valve replacement without modification of these valves and without the need for removal or
20 significant retraction of the ribs.

The replacement valve may be secured at the native valve position in various ways, but is preferably secured using sutures. The sutures are applied to the aortic valve annulus using elongated thoracoscopic needle drivers or other known types of thoracoscopic suture placement devices positioned through a percutaneous access port. Usually, a plurality of sutures are applied to the annulus, drawn out of the chest cavity, and then applied to the sewing ring of the valve prosthesis outside of the chest. The valve prosthesis is then slid along the sutures through the access port and placed against the native valve annulus using the delivery handle or other appropriate thoracoscopic instrument. A knot is formed in each suture outside of the chest, and
25 the knot is pushed along the suture through the access port and against the sewing ring of the valve prosthesis using a thoracoscopic knot pusher. The free ends of the suture are then trimmed using thoracoscopic scissors.
30

For securing bioprosthetic valves and other types of replacement valves, it may be desirable to use a single suture to form a running stitch between the sewing ring and the native valve annulus. In these cases, with the valve held in place at or near the aortic position using the delivery handle, thoracoscopic needle drivers may be

5 positioned through an access port and used to drive a needle alternately between the native annulus and the sewing ring of the replacement valve. The suture is then tied off and trimmed using thoracoscopic instruments.

Once the replacement valve has been secured at the aortic valve position, the aortic incision must be closed. Thoracoscopic needle drivers are introduced through a

10 percutaneous access port and used to drive a suture back and forth across the incision from end to end in a running stitch. The suture is then tied off and trimmed.

With the aortic incision closed, the patient's heart is restarted by removing the aortic occlusion device, whether an external clamp, endovascular aortic occlusion catheter, or other means, from the ascending aorta. If placed through a puncture in a

15 wall of the aorta, the puncture is closed with a purse-string suture or running stitch using thoracoscopic needle drivers. Warm oxygenated blood delivered to the arterial system by the arterial cannula is thereby allowed to flow into the ascending aorta and to perfuse the myocardium via the coronary arteries. Normal heartbeat will ordinarily resume spontaneously. If not, electrical defibrillation may be administered. Once

20 normal heartbeat has resumed, any retractors, trocars, or other devices in the percutaneous access ports are removed, and chest incisions are closed with sutures or adhesive strips. The patient is gradually weaned from cardiopulmonary bypass, all arterial and venous cannulae are removed, and arterial and venous punctures are closed. The patient is then recovered from anesthesia.

25 A further understanding of the nature and advantages of the invention will become apparent from the following detailed description taken in conjunction with the drawings.

Brief Description of the Drawings

30 Figure 1 is an anterior view of a patient's chest schematically illustrating an endovascular system for inducing cardioplegic arrest and establishing cardiopulmonary bypass according to the invention.

Figure 2 is a close-up view of a patient's heart and aorta showing the placement of an endoaortic catheter in the system of Figure 1.

Figure 3 is an anterior view of a patient's chest schematically illustrating a first embodiment of a thoracoscopic system for inducing cardioplegic arrest and
5 establishing cardiopulmonary bypass according to the invention.

Figure 3A is an anterior view of a patient's chest schematically illustrating a technique of gaining access to the aorta according to the invention.

Figure 4 is a close-up view of a patient's heart and aorta illustrating the placement of a thoracoscopic balloon cannula in the system of Figure 3.

10 Figure 5 is an anterior view of a patient's chest schematically illustrating a second embodiment of a thoracoscopic system for inducing cardioplegic arrest and establishing cardiopulmonary bypass according to the invention.

Figure 6 is a close-up view of a patient's heart and aorta illustrating the placement of a thoracoscopic clamp in the system of Figure 5.

15 Figure 7 is an anterior view of a patient's chest schematically illustrating a third embodiment of a thoracoscopic system for inducing cardioplegic arrest and establishing cardiopulmonary bypass according to the invention.

Figure 8 is a close-up view of a patient's heart and aorta illustrating the placement of a detachable thoracoscopic clamp and applicator in the system of Figure
20 7.

Figure 9 is an anterior view of a patient's chest schematically illustrating the formation of an aortotomy in the ascending aorta according to the invention.

Figure 10 is a close-up view of a patient's heart and aorta illustrating the formation of an aortotomy in the ascending aorta according to the invention.

25 Figure 11 is an anterior view of a patient's chest schematically illustrating retraction of the aortotomy according to the invention.

Figure 12 is a view of the aortotomy and the aortic valve through an oval-shaped access port placed in an intercostal space in the patient's chest, illustrating the placement of sutures for retraction of the aortotomy according to the invention.

30 Figure 13 is a view of the aortotomy and the aortic valve through an oval-shaped access port placed in an intercostal space in the patient's chest, illustrating the removal of the aortic valve leaflets according to the invention.

Figure 14 is a close-up partial cross-section of the left ventricle of the heart and the aorta showing a catcher placed in the left ventricle to catch pieces of valve leaflet and debris removed from the native valve annulus according to the invention.

- 5 Figure 15 is a view of the aortotomy and the aortic valve through an oval-shaped access port placed in an intercostal space in the patient's chest, illustrating the removal of calcific and fibrous material from the native valve annulus according to the invention.

- 10 Figure 16 is a transverse cross-sectional view of a portion of the patient's chest and heart illustrating the use of a valve sizing device for sizing the native valve annulus according to the invention.

Figure 17 is a transverse cross-sectional view of a portion of the patient's chest and heart illustrating the placement of sutures in the native valve annulus according to the invention.

- 15 Figure 18 is a view of the aortotomy and the aortic valve through an oval-shaped access port placed in an intercostal space in the patient's chest, illustrating the placement of sutures in the native valve annulus according to the invention.

Figure 19 right lateral elevational view of the patient's chest illustrating the placement of sutures through a prosthetic valve according to the invention.

- 20 Figure 20 is a transverse cross-sectional view of a portion of the patient's chest and heart illustrating the positioning of a prosthetic valve into the chest through an access port according to the invention.

Figure 21 is a right lateral elevational view of the patient's chest with a portion of the chest cut-away illustrating the placement of the prosthetic valve at the native valve position in the heart.

- 25 Figure 22 is a view of the aortotomy and the aortic valve through an oval-shaped access port placed in an intercostal space in the patient's chest, illustrating the tying and trimming of sutures to secure a prosthetic valve in the heart according to the invention.

- 30 Figure 23 is a view of the aortotomy and the aortic valve through an oval-shaped access port placed in an intercostal space in the patient's chest, illustrating the closure of the aortotomy according to the invention.

Figure 24 is a perspective view of an alternative embodiment of a delivery handle according to the invention holding an element schematically representing a valve sizing disk or prosthetic valve.

5 Figure 25 is a perspective view of the delivery handle of Figure 24 illustrating the element pivoted into an orientation suitable for positioning through an intercostal access port.

Figure 26 is a side cross-sectional view of the delivery handle of Figures 24 and 25.

10 Figure 27 is a perspective view of an additional embodiment of an access port through which a prosthetic valve may be positioned into the chest according to the invention.

Figure 28 is a perspective view of the access port of Figure 27 showing deployment of a retention element for retaining the access port in the chest wall.

15 Figure 29 is a perspective assembly view of the access port of Figures 27-28.
Figure 30 is a perspective view of an obturator for use in conjunction with the access port of Figures 27-29.

Figures 31A-31B are side cross-sectional views of the obturator of Figure 30 illustrating the actuation a means for retracting the retention means of the access port of Figures 27-29.

20 Figure 32 is a perspective view of the delivery handle of Figures 24-26 including an alternative embodiment of a valve holder according to the invention.

Figure 33A is a side assembly view of a distal portion of the delivery handle and valve holder of Figure 32.

Figure 33B is an end view of the valve holder of Figure 32.

25 Figure 34 is a perspective view of a bileaflet mechanical heart valve useful in conjunction with the devices and methods of the invention.

Figure 35 is a perspective view of a further embodiment of a valve holder according to the invention holding the bileaflet mechanical heart valve of Figure 34.

30 Figures 36A-36C are side, bottom, and proximal end views, respectively of the valve holder of Figure 35.

Figure 37 is a perspective view of an access port and illumination device constructed in accordance with the principles of the invention.

Figures 38-40 are cross-sections taken along the lines 38-38, 39-39 and 40-40, respectively, of Figure 37.

Figure 41 is a transverse cross-section of an alternative embodiment of an access port and illumination device according to the invention.

- 5 Figure 42A is a front view of an alternative embodiment of an access port having a channel through which an illumination or visualization device may be inserted.

Figure 42B is a transverse cross-section taken along line 42B-42B of Figure 42A.

10

Detailed Description of Specific Embodiments

Specific embodiments of the devices and methods of the invention will now be described in connection with aortic valve replacement procedures. However, it will be understood to those of ordinary skill in the art that a wide variety of procedures 15 may be performed on a variety of body structures without departing from the scope of the invention. These include, in addition to surgery of the aortic valve via the aorta, interventions in the coronary arteries, left ventricle, mitral valve, left atrium, or pulmonary vein via the aorta, interventions in the right atrium, tricuspid valve, right ventricle, pulmonary valve or pulmonary artery via the superior vena cava or inferior 20 vena cava, as well as interventions in various other organs via vessels in communication with those organs. The types of interventions which can be performed include not only aortic valve repair and replacement, but catheter interventions in the coronaries such as angioplasty, atherectomy, stent placement or endoarterectomy, electrophysiological interventions within the heart such as mapping 25 and ablation, transmyocardial revascularization using a laser placed within the heart, repair of septal defects and patent ductus arteriosus using patch placement or other defect closure devices placed in the right or left chambers of the heart, repair or replacement of the mitral, tricuspid or pulmonary valve including placement of annuloplasty rings and prosthetic valves, reattachment of chordae tendonae, 30 commissurotomy, and quadrangular resection, incision of the atrial or ventricular wall for the performance of a Cox maze procedure in the treatment of atrial fibrillation, and other procedures. The principles of the invention will apply to the performance of

these procedures in much the same way as to the performance of aortic valve replacement, which is now described with reference to Figures 1-36.

- The patient is first prepared for aortic valve surgery by putting the patient under general anesthesia, establishing cardiopulmonary bypass (CPB) and inducing
- 5 cardioplegic arrest. General anesthesia is induced in a conventional manner. A preferred technique for accomplishing CPB and cardioplegic arrest which does not require a sternotomy, thoracotomy, or other opening in the patient's chest is illustrated in Figure 1. Additional aspects of the systems and methods for inducing cardioplegic arrest described here may be found in patent application Serial Nos. 08/282,192, filed
- 10 July 28, 1994, now U.S. Patent No. 5,584,803 and 08/486,216, filed June 7, 1995, now U.S. Patent No. 5,766,151, the complete disclosures of which are hereby incorporated herein by reference.

A cardiopulmonary bypass system 20 includes a venous cannula 22 which is placed in a femoral vein 24 in the groin area or in another peripheral vein such as an

15 internal jugular vein or subclavian vein, located in the neck. While illustrated in a shorter configuration, the venous cannula may be long enough to extend from the femoral vein into the inferior vena cava, into the right atrium of the heart or through the right atrium into the superior vena cava. The system also includes an arterial return cannula 26 placed in a femoral artery 28 or in another peripheral artery such as

20 the subclavian or brachial artery in the neck or armpit. The arterial return cannula 26 is generally long enough so that it extends sufficiently into the femoral artery to avoid backing out of the artery but as short as possible to reduce damage to blood delivered through the arterial return cannula. Both venous cannula 22 and arterial return cannula 26 are configured to be placed into the femoral vein and femoral artery,

25 respectively, either by surgical cut-down, or by a percutaneous technique such as the Seldinger technique.

Venous cannula 22 and arterial return cannula 26 are connected to a CPB pump and oxygenator 30 of well-known construction. CPB pump and oxygenator 30 oxygenates the deoxygenated blood withdrawn from the patient's venous system

30 through venous cannula 22, and pumps the oxygenated blood back into the patient's arterial system via arterial return cannula 26. In this way, circulation and re-oxygenation of the patient's blood may be maintained while the heart is temporarily arrested.

Cardioplegic arrest may be induced using any of several techniques. One preferred technique is illustrated in Figures 1 and 2. In this technique, an endoaortic catheter 32 is introduced by surgical cut-down or by a percutaneous technique into a peripheral artery, which may be the femoral artery 34 as illustrated, or a brachial or

5 subclavian artery. Endoaortic catheter 32 is configured to be advanced transluminally, usually over a guidewire (not shown), from femoral artery 34 into the aorta until its distal end 36 is positioned in the ascending aorta 38 between the coronary ostia (not shown) just downstream of the aortic valve and the brachiocephalic artery 40. Endoaortic catheter 32 has an expandable member 42

10 mounted near its distal end 36 which, as shown in Figure 2, is configured to expand into sealing engagement with the inner wall of the ascending aorta 38 to block blood flow through the aorta without occluding either brachiocephalic artery 40 or the coronary ostia. In a preferred embodiment, expandable member 42 is an elastomeric balloon in communication with an inflation lumen 43 extending through endoaortic

15 catheter 32 to a delivery device such as syringe 46 for delivering an inflation fluid such as saline or radio-opaque contrast solution to expand expandable member 42 until completely occluding the aorta. The elastomeric balloon preferably is short in the axial direction, being disc-shaped (a short cylinder), donut-shaped (toroidal), ellipsoidal, or other shortened shape to minimize the amount of the ascending aorta

20 which is occupied by the balloon so that the surgeon has the maximum room to work upstream of the balloon. In one embodiment, expandable member 42 has an axial length between its proximal and distal ends of about 1-40 mm, preferably about 1-20 mm, and an expanded outer diameter in the radial direction of about 10 to 60 mm, preferably about 30-40 mm.

25 In a particularly preferred embodiment, arterial return cannula 26 includes an additional hemostatic port (not shown) at its proximal end that allows endoaortic catheter 32 to be slidably positioned through the blood return lumen of the arterial return cannula. Arterial return cannulae having such a configuration are disclosed in copending application Serial No. 08/282,192, filed July 28, 1994, now U.S. Patent

30 No. 5,584,803, which is incorporated herein by reference.

With expandable member 42 occluding the ascending aorta 38, a cardioplegic fluid is delivered from a cardioplegic fluid supply 48 through a delivery lumen 44 in endoaortic catheter 32 and a port 51 at its distal end 36 into the ascending aorta distal

- to expandable member 42 so that the cardioplegic fluid flows into the coronary arteries to perfuse the myocardium. The cardioplegic fluid preferably includes a cardioplegic agent such as potassium chloride mixed with blood and cooled to a low temperature, e.g. 5-20°C. Upon perfusion of the myocardium with cardioplegic fluid,
- 5 heart contractions will quickly cease. Circulation of oxygenated blood to organs and tissues other than the heart is maintained by cardiopulmonary bypass system 20. Expandable member 42 prevents the oxygenated blood delivered by arterial return cannula 26 from reaching the coronary arteries, which would allow the blood to perfuse the myocardium and revive the heart.
- 10 Periodically, it may be necessary to remove fluids from the ascending aorta 38 during the procedure. Such fluids may be withdrawn through delivery lumen 44 of endoaortic catheter 32 and diverted through a valve 47 to a filter and recovery system 49, which removes impurities from the blood and directs the blood to cardiopulmonary bypass system 20 where it is delivered back into the arterial system.
- 15 Alternatively, a separate cardiotomy suction probe may be introduced through an access port and through the aortic wall to remove such fluids. Endoaortic catheter 32 preferably also includes a pressure port 53 near its distal end 36 in communication with a pressure lumen extending to the proximal end of the catheter where it may be connected to a pressure measurement device 50, allowing pressures in the ascending aorta distal to expandable member 42 to be monitored during the procedure.
- 20 In addition to delivery of cardioplegic fluid in the "antegrade" manner via endoaortic catheter 32 as just described, it is usually desirable to deliver cardioplegic fluid in a "retrograde" manner through the coronary sinus during the aortic valve replacement procedure. For this purpose, a coronary sinus catheter 52 is placed into a peripheral vein 54, preferably the internal jugular vein or subclavian vein in the neck,
- 25 and advanced through the superior vena cava into the right atrium, where it is maneuvered into the coronary sinus (not illustrated). Coronary sinus catheter 52 has a balloon or other expandable member 58 near its distal end 60 which may be expanded by means of a syringe 62 to occlude the coronary sinus during fluid delivery. A
- 30 delivery lumen (not pictured) extends through the coronary sinus catheter 52 to a port at its distal end 60 to allow delivery of a cardioplegic fluid, which will usually be similar to that described above used in antegrade delivery. Coronary sinus catheter 52 may also include a pressure port near distal end 60 and a pressure lumen extending to

its proximal end for monitoring pressure distal to expandable member 58. Other aspects of coronary sinus catheters and retrograde cardioplegia techniques useful in connection with the present invention are disclosed in copending application Serial No. 08/372,741, filed January 12, 1995, now U.S. Patent No. 5,558,644, which is

5 hereby incorporated herein by reference.

In a preferred technique, after an initial infusion of cardioplegic fluid through endoaortic catheter 32 to induce cardioplegic arrest, most subsequent infusions are performed retrograde through coronary sinus catheter 52. To maintain cardioplegic arrest, cardioplegic fluid is preferably delivered in periodic infusions at, for example,

10 600 ml volumes delivered in about 120 to 180 seconds at 15 minute intervals.

Between infusions, expandable member 58 of coronary sinus catheter 52 is preferably deflated to allow fluid to drain from the coronary sinus.

In an alternative technique for inducing cardioplegic arrest, devices are introduced thoracoscopically through access ports between the ribs to occlude the

15 ascending aorta and, optionally, to deliver cardioplegic fluid into the ascending aorta upstream of the occluded area. In these thoracoscopic techniques, the pericardium is first opened to expose the ascending aorta. As illustrated in Figure 3A, several access ports 71, such as trocar sleeves or other tubular cannulae, are placed in intercostal spaces I between ribs R. A thoracoscope 73 of conventional construction and having

20 a video camera 75 mounted to its proximal end may be placed through one of access ports 71 for visualizing the procedure, or the surgeon may look directly into the chest through one of access ports 71. Thoracoscopic scissors 77 and graspers 79 are introduced through access ports 71 and used to create an incision 81 approximately 4-

10 cm in length in the anterior side of the pericardium 83 overlying the aorta 85 so

25 that the ascending aorta 87 and upper anterior side of the heart 89 are exposed.

Thoracoscopic scissors 77 and graspers 79 may have any of various well-known constructions, including those described in copending application Serial No. 08/194,946, filed February 14, 1994, now U.S. Patent No. 5,501,698, which is hereby incorporated herein by reference.

30 In a first embodiment of a thoracoscopic technique for arresting the heart, illustrated in Figs. 3-4, an expandable member 64 such as an elastomeric balloon is positioned in the ascending aorta 66 through a penetration in a wall of the aorta. Expandable member 64 will be shaped and dimensioned to allow complete occlusion

of ascending aorta 66 without blocking blood flow into the brachiocephalic artery 78 or the coronary ostia. Additionally, expandable member 64 will be as short as possible in the axial direction (along the central axis of the aortic lumen) to minimize its space requirements in the ascending aorta, preferably having a short cylindrical, 5 discoid, ellipsoid, donut or toroidal shape with an axial length of about 1-40 mm, preferably about 1-20 mm. Expandable member 64 is attached to a distal end 68 of a shaft 70, which may be a rigid or flexible biocompatible metal or polymer. Shaft 70 extends through the penetration in the aortic wall and out of the chest through an access port 72 between the ribs R. Shaft 72 is at least about 6 cm, preferably about 10 10-20 cm, in length so that its proximal end 76 is outside of the chest when expandable member 64 is in the ascending aorta 66 between the brachiocephalic artery 78 and the coronary ostia (not shown).

Access port 72, as with other access ports referred to in this application, is illustrated as a tubular cannula or trocar sleeve, but may alternatively comprise a 15 wound retractor with rigid blades or flexible adhesive strips for retracting tissue to create a small opening between the ribs. Instruments may alternatively be positioned directly through a puncture or incision between the ribs without a retractor, cannula or trocar, but usually some means of retracting tissue is desirable to prevent tissue damage and to facilitate introduction and manipulation of instruments. In some cases, 20 it may be necessary to cut or remove one or more of the costal cartilages that connect the ribs to the sternum, to allow a slightly greater degree of rib retraction. However, in most cases, the access ports will be configured to facilitate introduction of surgical instruments, visualization devices, valve prostheses, and other devices used in the various procedures of the invention without removing the ribs R or sternum S, and 25 preferably without retracting or cutting the ribs R significantly. Thus, the access ports will have a transverse profile suitable for positioning within an intercostal space I between two adjacent ribs R, which typically has a width (the distance between adjacent ribs R) of about 10-25 mm in normal adult patients, without cutting or removing the ribs, and without retracting the ribs more than about 1-2 cm from their 30 natural, undeflected positions. In many cases, the access ports may be circular in cross-section with an outer diameter of less than about 12 mm so as to be easily positionable within an intercostal space I. In other cases the access ports may have a

cross-sectional shape other than circular and may have a slightly larger transverse dimension to accommodate specialized instruments or prostheses, as described below.

- As shown in Figure 4, shaft 70 includes a delivery lumen 80 extending from a first connector 82 at proximal end 76 to a delivery port 84 at distal end 68, through which cardioplegic fluid may be delivered into ascending aorta 66. If expandable member 64 is a balloon, shaft 70 also has an inflation lumen 86 extending from a second connector 88 to the interior of expandable member 64, through which an inflation fluid such as saline or contrast solution may be delivered into the balloon. In addition, shaft 70 may optionally include an arterial return lumen 90 extending from a third connector 92 at proximal end 76 to an arterial return port 94 at distal end 68, through which oxygenated blood may be delivered into the aorta downstream of expandable member 64. Third connector 92 may be connected with tubing to the outlet of cardiopulmonary bypass system 20, allowing arterial return lumen 90 to be used in place of or as a supplement to the use of separate arterial return cannula 26 of Fig. 1. Shaft 70 may also include a pressure lumen (not shown) extending from proximal end 76 to a pressure port (not shown) at distal end 68 to allow pressure monitoring in ascending aorta 66 upstream of expandable member 64.

Shaft 70 is dimensioned so as to pass easily through access port 72 between ribs R, while having sufficient cross-section that lumens 80, 86 and 90 are large enough to perform their respective functions. Usually shaft 70 will have an outer diameter of less than about 12 mm, preferably less than about 10 mm. Delivery lumen 80 must be large enough in cross-section to allow cardioplegic fluid to be delivered at a sufficient flow rate to induce and maintain cardioplegic arrest, preferably allowing cooled cardioplegic fluid containing blood, usually having a viscosity of about 1-4 centipoise, to be delivered at a flow rate of at least about 200 ml/min at a pressure no more than about 300 mmHg. Thus, delivery lumen 80 has a cross-sectional area of about 0.5-8 mm², preferably about 0.5-2.0 mm². Arterial return lumen 90 is preferably large enough to allow blood to be delivered at flow rates adequate to maintain full cardiopulmonary bypass with the heart arrested (preferably without the use a separate arterial return cannula), having a cross-sectional area of about 12-75 mm², and preferably about 25-50 mm². In addition, inflation lumen 86 must be large enough to allow saline or other inflation fluid to be delivered at flow rates sufficient to inflate expandable member 64 in less than about 30 seconds,

preferably less than about 10 seconds, having a cross-sectional area of about .1-5 mm², preferably about 1-3 mm².

- A second embodiment of a thoracoscopic technique for inducing cardioplegic arrest is illustrated in Figs. 5-6. In this technique, an external clamp 98 is placed
- 5 around the ascending aorta 100 to occlude the aortic lumen 102 just upstream of the brachiocephalic artery 104. Clamp 98 is attached to a distal end 106 of a shaft 108 which is long enough to extend out of the chest through an access port 110 between ribs R, having a length of at least about 10 cm, preferably 20-30 cm. An actuator 112 is attached to proximal end 114 of shaft 108 to allow clamp 98 to be opened and
- 10 closed from outside of the chest. Actuator 112 includes a pair of movable handles 116 with finger loops 118, and a locking mechanism 120 which may comprise a pair of overlapping fingers 122 with transverse teeth (not shown) which interlock with one another. Clamp 98 includes a first jaw 124 fixed to shaft 108, and a second jaw 126 fixed to an inner shaft (not shown) extending through the interior of shaft 108 and
- 15 rotatable relative to shaft 108. One of handles 116 is fixed to the proximal end of shaft 108, while a second of handles 116 is fixed to a proximal end of the inner shaft, so that by pivoting handles 116 relative to one another, the inner shaft rotates relative to shaft 108, opening or closing jaws 124, 126. Other aspects of thoracoscopic clamping devices suitable for use in the method of the invention are described in U.S.
- 20 Patent No. 5,425,705, which is incorporated herein by reference.

In order to deliver cardioplegic fluid into the ascending aorta, several alternative techniques may be used. In one technique, illustrated in Figs. 5-6, a delivery cannula 130 may be positioned through an inner lumen of shaft 108 so that a needle 132 at the distal end of the delivery cannula extends distally of distal end 106 of shaft 108, generally parallel to and spaced apart from jaws 124. Jaws 124 may be curved or angled away from shaft 108 so that the portions of the jaws that extend around the aorta are offset from needle 132 to allow needle 132 to be placed through shaft 108 and penetrate the aortic wall upstream from jaws 124. Delivery cannula 130 has an inner lumen extending from its distal end to its proximal end which may be connected to a cardioplegic fluid source. In one embodiment, a connector 134 is provided near the proximal end of delivery cannula 130 which connects to a connector on the proximal end of shaft 108 to fix the delivery cannula in position relative to clamp 98. In this way, after clamp 98 has been closed on ascending aorta 100 to

occlude the aortic lumen 102, delivery cannula 130 may be positioned through shaft 108 to penetrate the aortic wall with needle 132, allowing cardioplegic fluid to be delivered upstream of clamp 98. The inner lumen of delivery cannula 130 will be configured to facilitate delivering cardioplegic fluid containing blood at a rate of at

- 5 least about 200 ml/min and a pressure of no more than about 300 mmHg, having a cross-sectional area of at least about 0.5 mm², and preferably 0.5-2.0 mm². Delivery cannula 130 may alternatively be independent of clamp 98 and shaft 108, and placed through a separate access port rather than being placed through shaft 108.

Alternative techniques of delivering cardioplegic fluid are described in U.S.

- 10 Patent No. 5,425,705, which has been incorporated herein by reference. In one such technique, not illustrated here, an endovascular delivery catheter may be placed through a peripheral artery such as a femoral artery until its distal end is in the ascending aortic lumen 102 upstream of the brachiocephalic artery 104. Clamp 98 may then be actuated to close on the aorta around the endovascular delivery catheter,
- 15 which may be reinforced in its distal extremity to prevent collapsing. In this way, cardioplegic fluid may be delivered upstream of the external clamp 98 without requiring a puncture through the aortic wall. Such an endovascular delivery catheter may also include a pressure port and pressure lumen for monitoring pressure in the ascending aorta during the procedure.

- 20 In a further embodiment of a thoracoscopic aortic occlusion technique, illustrated in Figures 7-8, an external clamp 136 is placed around the ascending aorta 138 by a thoracoscopic clamp applier 140, closed on aorta 138 to block blood flow through the aortic lumen, then released from clamp applier 140, which may then be removed from the chest. Clamp 136 comprises a pair of movable jaws 142, 144 pivotably connected to each other by a pin 152. Jaws 142, 144 have proximal extremities 154, 156 proximal to pin 152 to which a locking mechanism 148 is mounted, which may comprise a pair of deflectable overlapping fingers 150 having transverse teeth 152 which interlock with one another to maintain clamp 136 in a closed position. A pair of detents 158 are disposed at the proximal ends of jaws 142,
- 25 144 and are adapted to receive the distal tips 160 of clamp applier jaws 162. Clamp 136 is configured to be positionable through an access port 146 or incision between ribs R. Access port 146 has a transverse cross-sectional width to fit between the ribs without requiring significant deflection or removal of the ribs, but may have a longer

transverse cross-sectional dimension parallel to the ribs to allow clamp 136 to be positioned through the access port when held by clamp applier 140.

- Clamp applier 140 has, as shown in Figure 7, an actuator 164 at its proximal end which comprises one or more movable leaves 166 pivotably mounted to a shaft 168. Leaves 166 are linked to clamp applier jaws 162 by a linkage 170, best seen in Figure 8, which may be a rod or wire slidably disposed in a lumen 171 within shaft 168, linked to a scissors mechanism 172 coupled to jaws 162. In this way, moving leaves 166 toward shaft 168 causes jaws 162 to move between an open position for releasing clamp 136 to a closed position for grasping and closing clamp 136. Clamp 136 is preferably biased into an open configuration by a torsion spring (not shown) around pin 152 or a compression spring (not shown) between proximal extremities 154, 156 of jaws 142, 144. In this way, once locking mechanism 148 is released by deflecting fingers 150 away from each other, clamp 136 will be urged open as clamp applier jaws 162 are opened. Other aspects and alternative configurations of clamp 136 and clamp applier 140 are disclosed in commonly-assigned copending application Serial No. 08/567,996, filed December 4, 1995, now U.S. Patent No. 5,618,307, which is hereby incorporated herein by reference.

With clamp 136 closed on the aorta to occlude blood flow through the aortic lumen, cardioplegic fluid may be delivered into the ascending aorta by means of a delivery cannula 176 placed into the chest through an access port 178 and having a needle 180 at its distal end for penetrating the aortic wall. Usually, a purse-string suture 182 will be placed in the aortic wall surrounding needle 180 using thoracoscopic needle drivers positioned through an intercostal access port. The purse-string suture 182 is cinched up around delivery cannula 176 to maintain hemostasis around the cannula. Alternatively, as discussed above, an endovascular delivery catheter (not illustrated) may be used which extends into the ascending aortic lumen transluminally from a peripheral artery such as the femoral, brachial, or subclavian artery. Clamp 136 is clamped around the aorta after the endovascular delivery catheter has been positioned so that the inner wall of the aorta seals against the outer wall of the delivery catheter. The delivery catheter may be reinforced in its distal extremity to resist collapsing under the force of clamp 136. The delivery catheter may alternatively have an expandable member such as a balloon near its distal end which may be expended in the ascending aorta like endoaortic catheter 32 of Figs. 1-2.

Clamp 136 may then be applied to the ascending aorta directly around the expandable member to achieve complete occlusion without excessive crushing or collapsing of the aorta. Clamp 136 may also be placed distally or proximally of the expandable member, or a clamp may be placed in either side, to prevent migration of the

5 expandable member as well as blocking blood flow.

In addition, retrograde delivery of cardioplegic fluid via the coronary sinus by means of an endovascular catheter introduced through a peripheral vein (described above) may be used instead of or in combination with antegrade delivery through a thoracoscopic or endovascular delivery catheter placed in the aorta.

10 It should be noted that, in some cases, it may be appropriate not to induce cardioplegic arrest, but instead to place the heart in a state of fibrillation. While this is usually not desirable because it is generally thought to provide inadequate protection of the myocardium, it may be induced using the devices and methods of the present invention. The patient is placed on cardiopulmonary bypass as described above

15 (without occluding the ascending aorta so as to arrest the heart), and the oxygenated blood returned to the arterial system is cooled to a sufficiently low temperature to induce fibrillation. An endovascular or thoracoscopic catheter may be placed in the ascending aorta as described above, and, without occluding the ascending aorta, drugs or blood may be delivered to the coronary arteries, and fluids may be removed to vent

20 the heart and aorta. Alternatively, one of the above-described aortic occlusion devices may be used to periodically induce fibrillation during the procedure by occluding the aorta temporarily without delivering the cardioplegic fluids that induce cardioplegic arrest, with intermittent periods of no occlusion so as to avoid ischemia.

While the remainder of the aortic valve replacement procedure is described

25 with reference to the use of clamp 136 and delivery cannula 176 for inducing cardioplegic arrest, it should be understood that any of the devices and techniques described above, as well as various other techniques not specifically described here, may be used for inducing cardioplegic arrest without departing from the scope of the invention.

30 Once cardioplegic arrest is induced, the patient is supported on cardiopulmonary bypass, and the pericardium has been opened as described above, an incision, or aortotomy, 184 is formed in the wall of ascending aorta 186 as shown in Figures 9-10. At this point, at least one, and usually at least three, access ports should

be placed in intercostal spaces I between ribs R on the right anterior side of the chest. One or two access ports 188 with outer diameter less than about 12 mm are placed in the first, second, or third intercostal space through which delivery cannula 176 and thoracoscope 73 (if utilized) are positioned. Another access port 190 with outer

5 diameter less than about 12 mm is placed in the third, fourth or fifth intercostal space through which various instruments used in the procedure may be positioned. An additional access port 192, which is specially-configured for positioning a replacement valve through its central lumen as described more fully below, is placed in the first, second, third or fourth intercostal space, depending upon patient size and

10 anatomy. As described above, access ports 188, 190, 192 may comprise trocar sleeves or other tubular cannulae, or simply incisions in which tissue is retracted apart to create a small opening using any of a variety of tissue retraction devices. Preferably, however, access ports 188, 190, 192 will not require cutting or removal of ribs or the sternum, and will not require significant retraction of the ribs, preferably

15 requiring less than about 2 cm of retraction from the ribs' natural, undeflected positions.

It should be noted that, in the absence of a large thoracic incision for access into the chest, some means of illuminating the chest cavity is usually necessary. A thoracoscopic light wand or a commercially-available thoracoscope or endoscope

20 having a fiber-optic channel which emits light from the distal end of the device may be placed through an access port for illumination. Alternatively, one or more access ports may have an illumination device mounted to it, as described below in connection with Figures 37-40.

Aortotomy 184 is created using thoracoscopic angled scissors 194 or a knife

25 (not shown) positioned through access port 192, assisted by means of thoracoscopic forceps 196 positioned through access port 190. Angled scissors 194 and forceps 196 may be commercially-available thoracoscopic instruments or may be constructed as described in copending applications Serial No. 08/194,946, now U.S. Patent No. 5,501,698, and Serial No. 08/281,962, now abandoned, which have been incorporated

30 herein by reference. Aortotomy 184 is approximately 6-8 cm in length, extending distally and slightly posteriorly along the anterior side of the aorta from a point at least about 10 mm, and preferably about 15 mm, downstream of the right coronary ostium.

- Aortotomy 184 is then retracted open as illustrated in Figures 11-12. In an exemplary embodiment, sutures 200 are placed in the aortic wall along the edges of aortotomy 184, preferably with a suture near each end of aortotomy 184 on each side of the incision. Each of sutures 200 has a needle 202 attached to an end thereof which
- 5 is driven through aortic wall 204 using thoracoscopic needle drivers 206 introduced through either access port 190 or access port 192. Needle drivers 206 may be commercially-available thoracoscopic instruments or may be constructed as described in the aforementioned patent applications, Serial Nos. 08/194,946, or 08/281,962, now abandoned. Sutures 200 preferably have a length of at least about 20 cm so that they
- 10 may be withdrawn from the chest cavity by passing needles 202 through the chest wall between ribs R or by snaring the sutures with a hook introduced through an intercostal space. Sutures 200 are tensioned in opposing directions to retract aortotomy 184 open and are then secured outside the chest with hemostats 208 or other suitable clamping device of conventional construction. Alternatively, sutures
- 15 200 may be secured to tissue within the chest cavity by passing needles 202 through such tissue and tying the sutures off, or by attaching the suture ends to a clip, clamp, hook or staple which can be fastened to tissue in the chest. With aortotomy 184 retracted open, the aortic valve 210 is fully exposed and visible through the inner lumen 212 of access port 192, as illustrated in Figure 12.
- 20 The leaflets 214 of the native aortic valve 210 are then removed using thoracoscopic curved or angled scissors 194 or knife (not illustrated), and forceps 196 positioned through access ports 190, 192, respectively. Leaflets 214 are grasped by forceps 196, retracted away from the valve annulus 216, and cut closely to the inner edge of valve annulus 216 without cutting into the valve annulus or the aortic wall.
- 25 During this process, it may be advantageous to provide a mechanism for catching any bits of valve leaflet, calcium or other debris that may fall into the left ventricle as the leaflets are excised. As illustrated in Figure 14, a catcher 220 may be placed through aortic valve 210 into the left ventricle 222 and positioned so as to catch any debris released in the leaflet removal or debridement process. Catcher 220
- 30 may comprise a flexible, porous mesh, foam, gauze, or screen constructed as a bag or pouch with an opening 222 on a top end 224 thereof. Top end 224 is configured to be positioned in the left ventricle just below the aortic valve, with the sides of catcher 220 engaging the ventricular wall 226. Preferably catcher 220 is collapsible into a

smaller shape suitable for positioning through access port 190 or access port 192, through aortotomy 184, and through aortic valve 210, and at least top end 224 is resiliently biased to return to an expanded configuration in which the outer sides of top end 224 engage ventricular wall 226. A flexible and resilient metal or elastomeric

5 ring 228 may be mounted to catcher 220 around opening 222 which may be radially collapsed during positioning, then released to allow the ring to expand outwardly to engage the ventricular wall. To facilitate positioning, catcher 220 may be collapsed and placed in a tubular sleeve or catheter (not shown) during positioning through the aortic valve, then ejected from the sleeve within the left ventricle. Alternatively,

10 thoracoscopic forceps or graspers positionable through an intercostal access port may be used to grasp and collapse catcher 220 and position it into the left ventricle. A suture or other flexible tether 230 is preferably attached to catcher 220 and extends out of the chest through an access port to allow catcher 220 to be retrieved after use. The aforementioned tubular sleeve may be guided over tether 230 back into the left

15 ventricle and catcher 220 then collapsed and retracted into the sleeve to facilitate removing the device from the chest.

Following removal of the aortic valve leaflets, any calcific deposits and any remaining leaflet tissue around the inner surface of valve annulus 216 are removed using thoracoscopic rongeurs 232. Rongeurs 232 have a split-shaft construction, 20 wherein two independent shaft members 234, 236 are longitudinally slidably relative to one another. A fixed jaw 238 is disposed at the end of shaft member 234, and a movable jaw 240 is pivotably mounted to the distal end of shaft member 236 by a first pin 242 and pivotably attached to shaft member 234 by a second pin 244. In this way, longitudinal translation of shaft member 236 relative to shaft member 234 by means 25 of an actuator (not shown) at the proximal end of the device pivots movable jaw 240 relative to fixed jaw 238. Fixed jaw 238 and movable jaw 240 have hollow or concave inner sides facing each other, and cutting edges 246, 248 along the periphery of their inner sides. This construction allows cutting edges 246, 248 to be positioned close to or against the inner surface of valve annulus 216 to excise any remaining 30 leaflet material or calcific deposits along the valve annulus. Any material removed is collected within the concave inner sides of jaws 238, 240. In a preferred embodiment, rongeurs 232 include a suction lumen through which a vacuum may be applied from the proximal end of the device to evacuate tissue and debris as it is cut from valve

annulus 216. In the split shaft design of Figure 15, for example, at least one of shaft members 234, 236 may be provided with an inner lumen in communication with the inner sides of jaws 238, 240 through which a vacuum may be applied to evacuate material cut by cutting edges 246, 248.

- 5 In addition, an irrigation lumen may be provided in one of shaft members 234, 236 to allow an irrigation fluid such as saline to be delivered to the inner surfaces of jaws 238, 240 to keep the jaws clean and free of debris. In one embodiment, a suction lumen is provided in one shaft member 234 and an irrigation lumen is provided in the other shaft member 236 to provide both irrigation and suction in the space between
- 10 jaws 238, 240.

- As an alternative to the use of thoracoscopic rongeurs 232, various other devices may be used for removal of calcific and fibrous material at the native valve position, including high-speed rotating cutters or grinders like those used in atherectomy and arthroscopy devices, lasers, and ultrasonic scalpels, any of which
- 15 may be equipped with irrigation or suction lumens.

- The valve annulus is then sized to determine the appropriate size for a replacement valve. As illustrated in Figure 16, a valve sizing device 250 is introduced through access port 192 into the ascending aorta 186 through aortotomy 184. Sizing device 250 includes a shaft 252 having a pivoting tongue 254 at its distal end and a handle 256 at its proximal end. A sizing disk 258 is releasably attached to tongue 254. An actuator button 260 is slidably mounted to handle 256 and is connected to tongue 254 by a linkage (not shown) such as a slidable rod extending through a passage in shaft 252. In this way, sliding actuator button 260 along handle 256 pivots tongue 254 from a first orientation in which the tongue is generally parallel to shaft
- 20 252 to a second orientation in which the tongue is perpendicular to shaft 252. Thus, for a generally cylindrical sizing disk having a central axis, sizing disk 258 is positionable in an orientation in which the central axis is perpendicular to the longitudinal axis of shaft 252, providing a minimum profile to allow the sizing disk to be introduced through lumen 212 of access port 192. Once inside the chest, sizing
- 25 disk 258 may be re-oriented using actuator button 260 so that the sizing disk is in an appropriate orientation for sizing valve annulus 216, usually with its axis about parallel to the longitudinal axis of shaft 252 as shown in Figure 16. A button lock 262 may also be provided on actuator button 260 to allow sizing disk 258 to be releasably

locked in a suitable orientation for sizing valve annulus 216. Other aspects of valve sizing devices suitable for use in the method of the invention are described in copending applications Serial No. 08/485,600 and Serial No. 08/281,962, which have been incorporated herein by reference.

- 5 Once positioned inside ascending aorta 186 through aortotomy 184 and oriented in an orientation suitable for sizing valve annulus 216, sizing disk 258 is positioned within valve annulus 216 to allow a comparison of the outer diameter of sizing disk 258 to the inner diameter of valve annulus 216. To see the sizing procedure, the surgeon may look directly at valve annulus 216 through lumen 212 of
- 10 access port 192 or a thoracoscope may be used for video imaging of the valve annulus. If the sizing disk is either larger or smaller than the valve annulus, sizing device 250 is removed from the chest and sizing disk 258 is removed from tongue 254 and replaced with another sizing disk of a different diameter. The process is repeated until the surgeon has identified the appropriate size of replacement valve to be
- 15 implanted. It should be understood that other techniques may be used for determining the annulus size, including endoscopic video imaging, transesophageal echocardiography, or thoracoscopic ultrasonic imaging, as well as using an adjustable valve sizer that may be placed within the valve annulus and adjusted in diameter until the appropriate size is determined.
- 20 When the size of the valve annulus has been determined, the appropriate replacement valve is then identified. A variety of replacement valves may be used in the method of the invention, including many of the more widely-accepted valves used in conventional open-chest aortic valve replacement procedures. These include mechanical valves such as the St. Jude Medical Mechanical Heart Valve (St. Jude
- 25 Medical, Inc., St. Paul, Minn.), the Carbomedics Prosthetic Heart Valve (Carbomedics, Inc., Austin, TX), and the Sorin Monostrut Heart Valve or Sorin Bicarbon Valve (Sorin Biomedical, Inc., Irvine, CA), as well as bioprosthetic or tissue valves, such as the Carpentier-Edwards Pericardial Bioprostheses or Carpentier-Edwards Model 2625 Porcine Bioprostheses (Baxter, Inc., Edwards CVS Division,
- 30 Irvine, CA), or Medtronic Hancock MO Bioprostheses or Medtronic Hall valve (Medtronic, Anaheim, CA). In addition, the method of the invention may be used to replace a diseased aortic valve with an autologous graft such as the pulmonary valve from the same patient, which may be removed thoroscopically from the patient's

pulmonary artery using thoracoscopic instruments and visualization devices positioned through access ports between the ribs. Allografts, such as an aortic valve removed from another donor patient's heart, may also be implanted using the methods of the invention. While the aortic valve replacement procedure of the invention will 5 be described with reference to a mechanical bileaflet valve such as the St. Jude Medical Mechanical Valve, it should be understood that the methods described are equally applicable to other types of mechanical valves, as well as to bioprosthetic valves, autografts and allografts.

In order to implant most mechanical valve prostheses, a plurality of sutures 10 264 are placed in the native valve annulus to form mattress stitches or inverted mattress stitches. As shown in Figures 17-18, sutures 264 are double-armed with arcuate needles 266 on both ends, and are placed in valve annulus 216 using a specialized rotational needle driver 268, described in detail in copending application Serial No. 08/594,869, entitled "Endoscopic Suturing Devices and Methods", which is 15 hereby incorporated herein by reference. Rotational needle driver 268 has a shaft 270 with a rotatable carriage 272 at its distal end a handle 274 at its proximal end. One of needles 266 is releasably held in carriage 272 such that the needle's sharp point 275 is exposed outside of the carriage. Carriage 272 is rotatable about a pin 276 in shaft 270. An actuator button 278 is slidably mounted to handle 274 and is coupled to 20 carriage 272 by a linkage (not shown) such as a slidable rod within a passage in shaft 270. In this way, sliding actuator button along handle 274 rotates carriage 272 about pin 276. Carriage 272 may be configured to drive sharp point 275 of needle 266 in either a distal or proximal direction, depending upon whether it is desired to drive the needle from the ventricle toward the aorta, or from the aorta toward the ventricle. In 25 the embodiment illustrated, rotational needle driver 268 is set up to drive needle 266 from the left ventricle 222 toward aorta 186. Carriage 272 holding needle 266 is positioned through access port 192, through aortotomy 184 and through valve annulus 216. Sharp point 275 of needle 266 is then positioned so as to penetrate the valve annulus a distance of about 1-5 mm from the inner edge of the annulus, as visualized 30 by looking through access port 192 or under thoracoscopic visualization. When the needle is properly positioned, actuator button 278 is moved along handle 274 to translate needle 266 through valve annulus 216. Once sharp point 275 emerges from the annulus within the aorta, the needle may be picked up with thoracoscopic needle

drivers 206 positioned through access port 192 (or through a separate access port). In an alternative embodiment, a needle pick-up mechanism (not shown) is provided on needle driver 268 to allow needle 266 to be picked up without the use of a separate instrument, as described in the above-mentioned patent application Serial No.

- 5 08/594,869, entitled "Endoscopic Suturing Devices and Methods". When needle 266 is picked up, it is drawn through valve annulus 216 and withdrawn from the chest through lumen 212 of access port 192. A total of 10-20 sutures are placed in valve annulus 216 in this way.

Because of the large number of sutures that are placed in valve annulus 216, a
10 suture organizing device is provided outside the chest to keep the sutures orderly and free of tangles. In a preferred embodiment, a suture organizer 279 is disposed on the proximal end of access port 192 itself, the suture organizer including a plurality of radial slits 280, usually 12-24 pairs, arranged around the circumference of a rim 282 on access port 192. Slits 280 are configured to frictionally engage sutures 264 placed
15 into the slits, allowing each suture 264 to be placed in valve annulus 216, drawn out of the chest and placed in one of slits 280 until all of the sutures have been placed. Other aspects of suture organizer 279 are described in copending application Serial No. 08/485,600, which has been incorporated herein by reference.

In the case of certain bioprosthetic valves and other types of replacement
20 valves, techniques may be used for securing the valve to the heart which do not require a plurality of sutures to be placed in valve annulus 216. For example, some tissue valves are secured using a single continuous length of suture to make a running stitch around the sewing ring of the replacement valve. In other cases, staples, clips or other fastening devices may be used to secure the replacement valve to the native
25 annulus or adjacent tissue. In such cases, it may be unnecessary to place sutures or other fasteners in valve annulus 216 until after the replacement valve has been introduced into the chest and positioned at the aortic valve position.

With all of sutures 264 placed in valve annulus 216 and the ends of sutures 264 organized outside of the chest, each suture is placed through sewing ring 286 of
30 prosthetic valve 288, which is held by a delivery handle 290. Delivery handle 290 has an elongated shaft 291 and a handle 293 at its proximal end, and may be the same handle used in valve sizing device 250 described above in reference to Fig. 16, with sizing disk 258 removed from tongue 254. Prosthetic valve 288 is releasably held on a

holder 292 which includes a slot or aperture (not shown) configured to receive a tongue on delivery handle 290 similar to tongue 254 on valve sizing device 250.

Various other details concerning the construction of delivery handle 290, prosthetic valve 288, and holder 292 are described in copending application Serial No.

- 5 08/281,962 and application Serial No. 08/485,600, which have been incorporated herein by reference. A needle driver of conventional construction is used to grasp each of needles 266 and drive it through sewing ring 286. After each needle is driven through the sewing ring, it is secured by means of a hemostat 294 or by placement in a suture organizer positioned on or near the patient's chest.
- 10 Delivery handle 290 is configured to allow prosthetic valve 288, mounted to holder 292, to be delivered through an intercostal access port with minimal retraction of the ribs. If the annular sewing ring 286 has a central axis extending through it (generally defining the direction of blood flow through the valve), delivery handle 290 preferably holds prosthetic valve 288 in an orientation in which the central axis of sewing ring 286 is generally perpendicular to the longitudinal axis of shaft 291, wherein the prosthetic valve, holder, and delivery handle have a minimum profile in a direction perpendicular to the longitudinal axis of shaft 291. This will allow prosthetic valve 288 to be delivered through an intercostal space without removing or cutting the ribs or the sternum, and, in most patients, without retracting the ribs.
- 15
- 20 Certain types of prosthetic valves, particularly tissue valves, may have a larger profile due to the height of the valve commissures. However, even for these prosthetic valves, delivery handle 290 is adapted to hold the prosthetic valve in an orientation of minimum profile, allowing the prosthetic valve to be positioned into the chest with minimal retraction of the ribs, usually with less than about 10 mm of retraction of each rib from its natural, undeflected position, and preferably less than about 5 mm from the rib's natural, undeflected position.
- 25

To facilitate positioning prosthetic valve 288 through an intercostal space without interference with the ribs or tissue of the chest wall, the prosthetic valve is placed through inner lumen 212 of access port 192, as illustrated in Figure 20. Inner lumen 212 is specially adapted to allow prosthetic valve 288 to pass through it in an edge-first orientation. Preferably, the prosthetic valve is positioned through lumen 212 such that the central axis of sewing ring 286 is generally perpendicular to the longitudinal axis of inner lumen 212. At the same time, the overall profile of access

port 192 is minimized so as to require an incision in the chest wall of minimum size. In a preferred embodiment, the cross-section of inner lumen 212 in a direction perpendicular to its longitudinal axis has a cross-sectional length which is substantially greater than its cross-sectional width, with an oval, rectangular, 5 racetrack, elliptical, or other shape suitable for passage of prosthetic valve 288 in the edge-first orientation illustrated. The cross-sectional length will be just larger than the outer diameter of sewing ring 286, usually 17-35 mm, and the cross-sectional width will be just larger than the height of the valve parallel to the central axis of sewing ring 286, ranging from about 5-25 mm for mechanical valves, to about 15-30 10 mm for tissue valves.

Of course, a variety of other devices may be used to retract the chest wall tissue to allow prosthetic valve 288 to be introduced into the chest, including a soft tissue retractor designed to atraumatically retract tissue adjacent to an intercostal incision to create an opening in the chest without retracting the ribs. Alternatively, a 15 conventional retractor with a pair of movable parallel rigid blades may be positioned in an intercostal incision parallel to the ribs, the distance between the blades being adjustable to create an opening in the intercostal space of a desired width. Such an adjustable retractor may be desirable where the height and outer diameter of the prosthetic valve are both larger than the distance between the ribs in the intercostal 20 space through which the prosthetic valve is to be positioned, as may be the case with certain types of tissue valves. In this way, the ribs may be slightly retracted temporarily to allow the prosthetic valve to be positioned into the chest, and the retractor then re-adjusted to allow the ribs to return to their natural, undeflected positions for the remainder of the procedure, thus minimizing the trauma associated 25 with such retraction.

As prosthetic valve 288 is advanced into the chest, tension is maintained on sutures 264 by means of hemostats 294 or an assistant's hands so that sewing ring 286 slides along sutures 264 toward aortic valve annulus 216. Delivery handle 290 has a length sufficient to allow prosthetic valve 288 to be positioned at the native aortic 30 valve position in the heart with handle 293 remaining outside the chest, shaft 291 preferably having a length of at least about 15 cm. Once inside the chest, prosthetic valve 288 may be reoriented into an orientation suitable for securing the valve to valve annulus 216, i.e., an orientation in which sewing ring 286 may be positioned

parallel to and axially-aligned with valve annulus 216 (illustrated in Figure 21). Such reorientation may be accomplished by simply removing prosthetic valve 288 from delivery handle 290, but is preferably accomplished by pivoting prosthetic valve 288 relative to shaft 291 by sliding an actuator button 296 on handle 293. This pivots a

5 tongue at the distal end of shaft 291 to which holder 292 and prosthetic valve 288 are attached, in a manner like that described above with reference to valve sizing device 250 of Figure 16 (and described in copending application Serial No. 08/485,600, which has been incorporated herein by reference). Usually, prosthetic valve 288 is reoriented such that the central axis of sewing ring 286 is generally parallel to the

10 longitudinal axis of shaft 291 plus or minus about 30°, although the exact angular orientation may vary according to the location of access port 192 and patient anatomy.

Prosthetic valve 288 is positioned adjacent to the valve annulus 216 and then released from delivery handle 290, which may then be removed from the chest, as

15 illustrated in Figure 21. Prosthetic valve 288 is preferably released by cutting a suture (not shown) on holder 292 as frequently provided on conventional prosthetic valve holders. This allows a movable portion of holder 292 to pivot away from sewing ring 286, releasing the prosthetic valve from the holder, as described in greater detail in copending application Serial No. 08/281,962, which has been incorporated herein by

20 reference.

Referring now to Figure 22, knots 300 are formed in each of sutures 264 outside of the chest, and a thoracoscopic knot pusher 302 is used to push knots 300 along sutures 264 through lumen 212 of access port 192, through aortotomy 184 and against sewing ring 286 of prosthetic valve 288. Knot pusher 302 preferably has an elongated shaft 303 to which is attached a head 304 with a convex curvature on its distal end 306 and a pair of axial channels 308, 310 along its lateral sides, as described in copending application Serial No. 08/288,674, filed August 10, 1994, which is hereby incorporated herein by reference. One end of each suture is threaded through channel 308, a knot 300 is formed in the suture distally of head 304, and the other end of the suture is positioned in channel 310. While holding the ends of suture 264 in tension, knot pusher 302 is advanced toward prosthetic valve 288, engaging knot 300 with distal end 306 and sliding the knot along suture 264 until it is against sewing ring 286. Several knots are formed in each suture in this manner. The ends of

sutures 264, along with needles 266, are then trimmed off above knots 300, using thoracoscopic angled scissors 194 or other suitable cutting device.

- With prosthetic valve 288 successfully secured in the aortic valve position, the movable leaflets 312 may be tested for proper action by inserting a probe (not shown) 5 through an access port and exerting a gentle force against the outer edges of the leaflets. The probe may comprise an elongated shaft with an atraumatic tip of a soft elastomer suitable for contacting the valve leaflets, like that described in copending application Serial No. 08/485,600, which has been incorporated herein by reference. Alternatively, the probe may include an inner lumen extending to a port at its distal 10 end, the inner lumen being adapted for connection to a source of suction outside the chest, whereby suction may be applied to the valve leaflets to test for proper opening and closing.

- If leaflets 312 are functioning properly, aortotomy 184 may be closed. This may be accomplished, as illustrated in Figure 23, by suturing the opposing edges of 15 the aortic incision together using a conventional running stitch applied by means of thoracoscopic needle drivers 206 positioned through access ports 188, 190 or 192. Alternatively, an endoscopic stapler may be used to apply a series of staples across aortotomy 184.

- While aortotomy 184 is being closed, it will usually be desirable to remove 20 any air from within the left ventricle and ascending aorta 186 upstream of aortic clamp 136. This is accomplished by first reducing venous drainage of the heart via venous cannula 22 to allow blood to flow from the right side of the heart into the left ventricle, thereby filling the left ventricle with blood. This forces air out of the left ventricle into the ascending aorta. Preferably, the patient will be positioned so that 25 the superior or anterior aspect of the aortic arch is upward so that any air collects at a point where it can be suctioned out through delivery cannula 176. An irrigation fluid such as saline may also be delivered through delivery cannula 176 into the ascending aorta and left ventricle to assist in displacing air to the upper part of the ascending aorta near delivery cannula 176. Additionally, thoracoscopic instruments may be 30 positioned through intercostal access ports to depress and collapse the heart, forcing out any air in the left ventricle. Heart manipulation devices may also be positioned through an access port to lift and/or rotate the heart so that any air tends to flow

through the aortic valve into the ascending aorta, where it may be suctioned out. Further, small needles may be used to aspirate air from the left ventricle and/or aorta.

- In an alternative technique of keeping air out of the heart during the procedure, the chest cavity may be flooded with a gas such as carbon dioxide at the outset of the
- 5 procedure to prevent any air from entering the chest through the access ports. A gas delivery tube may be introduced through an intercostal access port, or a gas delivery lumen may be provided in a wall of one of the access ports themselves through which the gas is delivered. To facilitate maintaining the gas within the chest, the access ports may be provided with gaseous seals such as those commonly used in
- 10 laparoscopic trocar sleeves which provide a gas-tight seal both when an instrument is introduced through the port, as well as when the instrument is removed. These and other techniques for removing air from the heart and aorta are disclosed in copending application Serial No. 08/585,871, filed January 12, 1996, entitled "Methods and Apparatus for Preventing Air Embolism When Performing A Procedure On A
- 15 Patient's Cardiovascular System," which is incorporated herein by reference.

- With de-airing complete, cardiac function may be allowed to resume. The patient's head is temporarily tilted head-down to prevent emboli from entering the cerebral circulation. Aortic clamp 136 (or other aortic occlusion device) is removed from ascending aorta 186 to allow oxygenated blood delivered via arterial return
- 20 cannula 26 to flow into the ascending aorta and into the coronary arteries. To remove clamp 136, clamp applier 140 (Figures 7-8) is reintroduced into the chest via access port 192, and proximal extremities 154, 156 are engaged by clamp applier jaws 162 and actuated so as to release locking mechanism 148, allowing jaws 142, 144 to return to an open position. Clamp 136 is then withdrawn from the chest cavity. Oxygenated
- 25 blood is then permitted to flow through the coronary arteries to perfuse the myocardium, whereupon cardiac contractions will quickly resume. In the event that cardiac function does not return spontaneously, electrical defibrillation may be utilized to restore normal heart beat. Defibrillation electrodes may be placed on the heart via intercostal access ports, or external paddles of conventional construction
- 30 may be used on the surface of the chest, and an electrical charge may then be delivered to stimulate the heart.

When cardiac contractions have resumed, it may still be desirable to maintain suction through delivery cannula 176 so as to remove any air or other emboli which

may be present in the aorta or left ventricle. When it is believed that such emboli are no longer present, delivery cannula 176 is removed from ascending aorta 186 and purse-string suture 182 (Figure 8) is tightened securely and knotted to close the puncture in the aorta. Thoracoscopic needle drivers 206 may be used for this purpose.

- 5 Thoracoscopic scissors are then used to trim the ends of purse-string suture 182.

The patient is then weaned from cardiopulmonary bypass in the conventional manner, and venous cannula 22, arterial return cannula 24, coronary sinus catheter 52, any other catheters utilized in the procedure, and access port 188, 190, 192, are removed from the patient. Chest drainage tubes may be placed temporarily through 10 incisions used for access, or through additional incisions. All other thoracic and vascular punctures and incisions are closed, and the patient is recovered from anesthesia.

While the invention has been described in the context of aortic valve replacement, various other procedures may be performed using the methods of the 15 invention, including repair or replacement of the mitral, pulmonary or tricuspid valves; repair of atrial and ventricular septal defects and patent ductus arteriosus by means of stapling, suturing or patch-applying instrument positioned into the heart; transmyocardial revascularization by means of a laser introduced into the heart; electrophysiological mapping and ablation by means of a mapping and ablation 20 catheter positioned into the heart; performance of a Cox maze procedure by means of a cutting or ablation device positioned in the heart for transecting the atrial wall to correct atrial fibrillation; and pulmonary embolectomy by positioning a embolus-removal device into the pulmonary artery. Advantageously, in each such procedure, all instruments may be introduced into the heart either through intercostal access ports 25 or via blood vessels with the surgeon's hands outside the chest, eliminating the need for a median sternotomy or other form of gross thoracotomy.

Another exemplary embodiment of a delivery handle for positioning either a sizing disk or a replacement valve through an intercostal access port and into the native valve position is illustrated in Figures 24-26. In this embodiment, delivery 30 handle 320 comprises a shaft 322 having a distal end 324 and a proximal end 326. A sizing disk or a holder for releasably holding a replacement valve, represented schematically by cylindrical element 328, is pivotably mounted to distal end 324 by a

transverse pin 330. A pair of finger grips 332 are fixed to shaft 322 near proximal end 326, and an end cap 334 is slidably received over proximal end 326.

- As shown in Figure 26, a rod 336 extends through an inner lumen 338 in shaft 322. Rod 336 has a proximal end 340 fixed to end cap 334, and a distal end 342
- 5 rotatably pinned to element 328 at a point laterally offset from transverse pin 330. A spring 344 is disposed within a bore 346 within end cap 334 and engages the proximal end of shaft 322 to bias end cap 334 and rod 336 in the proximal direction. In this way, element 328 may be pivoted relative to shaft 322 by pushing end cap 334 distally with the thumb while the fingers are placed against finger grips 332. Element
- 10 328 is usually rotatable through an angle of at least about 45°, and preferably at least about 90°, relative to shaft 322. In a preferred embodiment, delivery handle 320 is configured to position element 328 in an orientation suitable for introduction through an intercostal access port without removing, cutting, or significantly retracting the ribs. As illustrated in Figure 25, element 328 is preferably movable into an
- 15 orientation in which the central axis AA extending axially through cylindrical element 328 is generally perpendicular +/-20° relative to the longitudinal axis LA of shaft 322. In this way, the profile of delivery handle 320 together with element 328 as seen from the distal end of the device is minimized. Element 328--whether a sizing disk or replacement valve--may be introduced through an intercostal access port (such as
- 20 access port 192 of Figures 7-24) in the orientation of Figure 25 by maintaining pressure against end cap 334. Once inside the chest, end cap 334 may be released, allowing element 328 to return to the orientation of Figure 24, wherein the element is in a suitable orientation for alignment with the native valve annulus for either sizing the annulus or implanting the replacement valve. Usually, element 328 will be
- 25 oriented such that central axis AA is at an angle of between -45° and 45°, and preferably about 0° +/- 20°, relative to the longitudinal axis LA of shaft 322.

Figures 27-29 illustrate an additional embodiment of an access port for retraction of tissue within an intercostal space so as to provide an open passageway through which a replacement valve may be positioned into the chest. Access port 350

30 comprises a tubular body 352 having an axial passage 354 configured to allow a replacement valve to be positioned through it without contacting the inner walls of the axial passage. Tubular body 352 is a metal or biocompatible polymer with sufficient rigidity to retract intercostal tissue and to retain a shape suitable for positioning a

replacement valve through the axial passage into the chest. Axial passage 354 preferably has a cross-sectional shape suitable for introducing a replacement valve or sizing disk through it in the edge-first orientation illustrated in Figure 25, such as oval, elliptical, racetrack, rectangular, trapezoidal, or other suitable shape. Axial

5 passage 354 will have a cross-sectional width orthogonal to a central axis AX of less than about 30 mm, usually about 10 mm-25 mm, and preferably about 15 mm-20 mm. The cross-sectional length of axial passage 354 orthogonal to central axis AX will be larger than the outer diameter of the replacement valve utilized, and usually substantially larger than the cross-sectional width of the axial passage, usually being

10 about 15 mm-50 mm, and preferably being about 25 mm-40 mm. Tubular body 352 has an exterior shape and dimensions suitable for positioning access port 350 in an intercostal space without cutting or removing the ribs, and preferably without significant retraction of the ribs from their natural, undeflected positions (e.g. less than about 10 mm of retraction). In an exemplary configuration, the outer surface of

15 tubular body 352 has a shape corresponding to that of axial passage 354 with a wall thickness therebetween of about 0.25-2 mm, preferably 0.75-1.25 mm. Of course, the exact size and shape of tubular body 352 will be determined by the size and shape of the replacement valve to be utilized in the procedure.

Access port 350 may further include a flange 356 on its proximal end which

20 engages the outer surface of the patient's chest. A suture organizer 358 is preferably mounted to flange 356, and includes an annular wall 360 with a plurality of radial slits 362 in spaced-apart locations around its circumference. Each slit 362 is configured to receive a suture thread and frictionally retain it as described above in connection with Figures 18-19.

25 Access port 350 additionally includes a retention mechanism 364 mounted to a distal extremity of tubular body 352 for retaining the access port in the chest wall. As illustrated in Figure 28, retention mechanism 364 comprises a sleeve 366 slidably mounted on tubular body 352 and coupled to flange 356 by a pair of tension springs 368, which may be elastomeric bands or cords. A retention element 370 is mounted

30 near the distal end of sleeve 366 and is collapsible for introduction through an intercostal space in the chest wall, and then expandable into a configuration in which the retention element engages the inner wall of the chest. In the exemplary configuration illustrated in the figures, retention element 370 comprises a continuous

flexible band 372 which extends through two pairs of slots 374 on opposing sidewalls of sleeve 366 forming two inner loops 376 in the interior of sleeve 366 and two outer loops 378 exterior to sleeve 366. Band 372 is preferably a resilient, flexible metal, plastic or elastomer which is biased into a fully expanded oval or circular ring shape.

- 5 By compressing outer loops 378 radially inward toward sleeve 366, a portion of band 372 slides through slots 374, enlarging inner loops 376 and collapsing outer loops 378 into the configuration illustrated in Figure 28. To expand outer loops 378, inner loops are pushed outwardly against sleeve 366.

An assembly view of access port 350 is illustrated in Figure 29. Annular wall

- 10 360 has a plurality of openings 380 formed around its circumference. An insert assembly 382 has a support ring 383 with a plurality of elastomeric inserts 384 attached thereto and configured to fit into openings 380. A lower end of each insert 384 is configured to be received in one of a plurality of slots (not shown) in flange 356 aligned with each opening 380. Each insert 384 has an enlarged lower end 386 which engages the lower surface of flange 356 to retain the insert within opening 380. In this way, the adjacent surfaces of inserts 384 and wall 360 within openings 380 form radial slits 362 (Figure 27). Inserts 384 will preferably have sufficient compliance to deflect slightly as a suture thread is drawn into slit 362, and sufficient resilience to maintain pressure against the thread to retain it in the slit.
- 15 20 Also attached to support ring 383 are tension springs 368, which may comprise resilient elastomeric bands or cords, extending distally through a pair of appropriately aligned slots (not shown) in flange 383. Sleeve 366 has a pair of ears 388 at its proximal end with axial passages through which tension springs 368 may extend. Each tension spring 368 has a flange or ledge 390 at its distal end which retains the tension spring in ear 388.

- 25 To facilitate expanding and collapsing retention element 370, the invention provides a specialized obturator for use with access port 350, illustrated in Figures 30-31. Obturator 392 has a shaft 394 shaped to occlude axial passage 354 of access port 350. A distal end 396 of shaft 394 is tapered to facilitate introduction through a puncture or incision in the chest wall. A handle 398 is fixed to the proximal end of shaft 394. A pair of hooks 400 are movably coupled to shaft 394 near distal end 396 and form a distally-open U-shaped channel 401 configured to receive inner loops 376 of band 372. As illustrated in Figures 31A-31B, hooks 400 are mounted to a pair of

actuators 402 pivotably mounted to handle 398 by a pin 404 such that actuators 402 move in a scissors-like manner. Actuators 402 each have an outwardly extending button 406 which extends through an aperture 408 in handle 398. Actuators 402 are biased outwardly by a torsion or U-shaped spring 410. In this way, pressing buttons 5 406 inwardly moves hooks 400 from the outward position illustrated in Figure 31A to the inward position illustrated in Figure 31B.

Obturator 392 further includes a locking mechanism 412 comprising a pivotable locking button 414 mounted within an opening 416 in handle 398. Locking button 414 has a foot 418 extending from a distal surface thereof. Each of actuators 10 402 has a notch 420 on a proximal surface thereof which is configured to receive foot 418. A torsion spring 422 biases locking button 414 in a clockwise direction. When actuators 402 are pivoted inwardly, foot 418 slides along the proximal surfaces of actuators 402 until notches 420 are aligned. This allows foot 418 to slide into notches 420, locking actuators 402 in the inward position, as shown in Figure 31B. The 15 locking mechanism is released by pushing on the proximal surface of locking button 414 on the side opposite that of foot 418, pivoting locking button 414 counterclockwise to remove foot 418 from notches 420.

In use, obturator 392 is positioned in axial passage 354 of access port 350 such that hooks 400 extend around inner loops 376 of band 372 to position the band in 20 channels 401. Buttons 406 are then pressed inwardly, drawing inner loops 376 inwardly and collapsing outer loops 378 against the outer surface of sleeve 366. Access port 350 may then be positioned through an incision or puncture through the chest wall between two ribs. When band 372 is inside the chest cavity, locking button 414 is released, allowing actuators 402 and hooks 400 to return to the outward 25 position. Outer loops 378 are thereby deployed into their expanded configuration, and obturator 392 may be removed from axial passage 354. Tension springs 368 pull sleeve 366 toward flange 356 on tubular body 352, compressing the chest wall between band 372 and flange 356. Access port 350 is thus firmly held in position during the procedure. To remove the access port from the chest, obturator 392 is re- 30 inserted into axial passage 354 such that hooks 400 engage inner loops 376, buttons 406 are pressed inwardly to collapse outer loops 378, and access port 350 is withdrawn from the intercostal incision.

Referring now to Figures 32-33, a preferred embodiment of a holder for an aortic valve prosthesis according to the invention will be described. As shown in Figure 32, holder 430 is attached to the distal end of delivery handle 320 in place of element 328, described above in connection with Figures 24-26. Holder 430 is

5 pivotable relative to shaft 322 from a first orientation of minimum profile suitable for introduction through an intercostal space, to a second orientation suitable for aligning the prosthetic valve with the native valve annulus so that it may be secured thereto. Preferably, as described above, in the first orientation, holder 430 is positioned such that the central axis of the prosthetic valve sewing ring is generally perpendicular to

10 the longitudinal axis of shaft 322, as shown in phantom in Figure 32. In the second orientation, holder 430 is preferably positioned so that the central axis of the prosthetic valve sewing ring is generally parallel to the longitudinal axis of shaft 322.

A configuration of holder 430 will be described which is appropriate for use with a mechanical bileaflet aortic valve prosthesis such as the St. Jude Medical

15 15 Mechanical Aortic Valve. However, it will be understood to those of ordinary skill in the art that holder 430 may be configured to accommodate a wide variety of prosthetic valves without departing from the scope of the invention. As shown in Figures 33A-33B, holder 430 is configured to hold prosthetic valve 432 from its downstream side with movable valve leaflets 434 in their closed position. In this position, valve

20 leaflets 434 form a V-shaped space within the interior of the valve surrounded by annular valve body 436 and sewing ring 438. Holder 430 therefore has a peaked or wedge-shaped distal surface 440 with angled faces 441A, 441B forming an angle α of between about 90° and 150°, which fits within the V-shaped space adjacent valve leaflets 434. An annular rim or flange 442 is configured to abut annular sewing ring

25 438 of prosthetic valve 432. A handle coupling 444 is attached to the proximal surface 446 of holder 430 and is configured to be attached to delivery handle 320. Handle coupling 444 has a transverse channel 448 as shown in Figure 33B configured to receive the distal end of shaft 322. A pair of holes 450, 452 extend through handle coupling 444 across channel 448 and may be aligned with holes 454, 456 in delivery

30 30 handle 320 so that pins may be inserted therethrough. In this way, by sliding rod 336, holder 430 pivots relative to shaft 320.

Prosthetic valve 432 may be removably attached to holder 430 in various ways. In a preferred embodiment, sutures are placed through sewing ring 438 and

through holder 430 and tied in order to secure the prosthetic valve to the holder. For this purpose, holder 430 may include holes, loops, eyelets or the like proximal to rim 442 through which sutures may be placed. Alternatively, holder 430 may be made of a soft elastomeric material through which a suture needle may be driven to secure the 5 suture to the holder. When it is desired to remove the prosthetic valve from holder 430, the sutures are cut with scissors or a knife.

Certain prosthetic valves are designed to allow the valve body and valve leaflets to be rotated relative to the sewing ring of the prosthesis after the sewing ring has been secured to the heart. Advantageously, once holder 430 has been removed 10 from prosthetic valve 432 and the prosthetic valve secured in the heart, holder 430 may be used to rotate valve body 436 along with leaflets 434 by repositioning holder 430 within the V-shaped space formed by leaflets 434 and rotating handle 320 about its longitudinal axis. A flat 458 is provided along the two sides of holder 430 which are positioned adjacent to side supports 459 of prosthetic valve 432, allowing torque 15 to be transmitted to valve body 436 rather than to the fragile valve leaflets 434.

Figures 34-36 illustrate an alternative embodiment of a holder according to the invention. In this embodiment, holder 460 is configured to hold a bi-leaflet mechanical valve from its upstream side for replacement of a diseased cardiac valve from the upstream side of the native valve, e.g., for replacement of the mitral valve 20 via an incision in the left atrium as described in copending application Serial No. 08/281,962 and Serial No. 08/485,600, which have been incorporated herein by reference. As shown in Figure 34, mechanical bileaflet valve 462 has a pair of leaflets 464 movably attached to a pair of upwardly extending side supports 465 on an annular valve body 466. A sewing ring 468 is attached to valve body 466. Leaflets 464 are 25 pivotable between an open position wherein the leaflets are nearly parallel, to a closed position wherein the inner edges of leaflets 464 abut one another and the curved outer edges of the leaflets abut the inner surface of annular valve body 466. As shown in Figures 35-36, holder 460 is configured to be positioned on the upstream side of valve 462 with leaflets 464 in the open position. Holder 460 has a distal end 470 having a 30 pair of crescent-shaped feet 472 for positioning between the outer (upstream) surface of each leaflet 464 and the inner surface of valve body 466. An arcuate channel 474 extends across distal end 470 between feet 472 which accommodates side supports 465 and the inner ends of leaflets 464. A rim 476 extends around the perimeter of

distal end 470 which abuts sewing ring 468 and/or valve body 466. Holder 460 is adapted for attachment to delivery handle 320 by a handle coupling 480 extending laterally from a proximal end of the holder. Handle coupling 480 has a pair of holes 482, 484 which may be attached to delivery handle 320 as described above in connection with Figures 33A-33B.

5 Prosthetic valve 462 may be releasably attached to holder 460 in various ways. In a preferred technique, holder 460 is constructed of a soft elastomer which allows a suture needle to be driven through it. In this way, one or more sutures may be placed through sewing ring 468 and through holder 460 and tied to secure the valve to the 10 holder. Alternatively, holder 460 may be a more rigid material and holes, eyelets, or loops may be mounted to the holder to which sutures may be secured. When valve 462 is to be released, the sutures are simply cut.

An additional embodiment of an access port according to the invention is illustrated in Figures 37-40. In this embodiment, access port 490 comprises a tubular 15 cannula 492 having a distal end 494, a proximal end 496, and a lumen 498 through which any of the replacement valves, valve holders and valve delivery devices described above may be positioned without interference. As described above in connection with Figures 27-29, lumen 498 is preferably oval-shaped, but the lumen 20 may be any of a variety of shapes suitable for introducing a prosthetic valve into the chest with minimal retraction of the ribs. Cannula 492 has a wall 500 constructed of a material having sufficient rigidity to retract intercostal tissue so as to provide an opening into the chest through which a replacement valve may be positioned. A rim 501 is provided at proximal end 496 which is adapted to engage the outer surface of the chest. An obturator (not shown) removably positionable within lumen 498 may 25 also be provided to facilitate introduction through the chest wall.

As best seen in Figures 38-39, a channel 502 extends axially through wall 500 between proximal end 496 and distal end 494. A plurality of axially-extending optical fibers 504 are distributed around channel 502 so as to surround lumen 498 and are potted, bonded or other wise fixed within channel 502 such that distal ends 506 of the 30 optical fibers are disposed near distal end 494 of the cannula and are pointing generally in the distal direction. Optical fibers 504 extend proximally through channel 502, through an annular space 508 within rim 501, and into a flexible cable 510 attached to rim 501 that has a protective, opaque jacket 511 surrounding the

optical fibers. An optical coupling 512 is fixed to the free end of cable 510 and is configured to be coupled to a conventional fiber optic light source of the type used for fiber optic lighting in endoscopes and the like, allowing light to be transmitted from the light source through optical fibers 504 and emitted from their distal ends 506.

- 5 In use, cannula 492 is positioned within a small incision between two ribs such that distal end 494 is within the chest cavity. Coupling 512 is connected to a light source so that light is emitted from optical fibers 504 so as to illuminate the chest cavity. Various surgical procedures may then be performed within the chest using instruments positioned through lumen 498 or through other access ports under
- 10 the illumination provided by optical fibers 504. For example, the various steps of an aortic valve replacement procedure as described above may be performed under illumination provided by access port 490. Advantageously, access port 490 may be positioned in alignment with the aortic valve to provide the optimum angle of illumination, while at the same time providing the optimum angle of approach to the
- 15 valve for introduction of instruments, valve sizers, and the prosthetic valve itself through lumen 498. The provision of optical fibers 504 on access port 490 may thereby eliminate the need for a separate light source within the body cavity for much of the procedure, reducing the number of access ports that are required.

- Optical fiber 504 may be mounted to access port 490 in various ways. In
- 20 addition to the annular arrangement of Figures 37-40, optical fibers 504' may also be mounted along one side of lumen 498', in a crescent-shaped channel 516 extending through cannula 492', as shown in Figure 41. Multiple channels (not shown) may extend along two or more sides of lumen 498 among which optical fibers 504 may be distributed. Alternatively, as shown in Figures 42A-42B, instead of mounting optical
 - 25 fibers to the access port, an open axial channel 518 may extend through cannula 492'' through which an endoscopic light wand or thoracoscope (not shown) having a light source mounted to it may be slidably inserted into the body cavity alongside lumen 498''.

- The access ports of Figures 37-42 may also include any of the features of the
- 30 access ports described above in connection with Figures 27-29, including having a suture organizer mounted to the proximal end of the access port for retaining sutures in an organized manner around lumen 498, or having a selectively deployable

retention device mounted near the distal end of the access port for engaging the inner wall of the chest (or other body cavity) to maintain the access port in position.

- While the above is a complete description of the preferred embodiments of the invention, various alternatives, substitutions, modifications and improvements are
- 5 possible without departing from the scope hereof, which is defined by the following claims.